REMARKS

The applicant respectfully requests reconsideration of claims 27-78 and consideration of new claims 79-94 in view of the foregoing amendment. The allowance of claims 27-28, 30-42, 47-57, 61, and 63-64, and the indication that claims 43, 45-46, 58-60, 62, 69-70, and 76-77 contain allowable subject matter, are noted and appreciated.

The foregoing amendment includes changes to claims previously presented, as follows:

1. Claim 29 is amended by replacing "device" with "implant," and by replacing "catheter" with "delivery device." The use of "delivery device" is intended to broaden the literal claim scope. The use of "implant" is intended to provide a better distinction relative to "delivery device."

2. Claims 43-46 and 59-60 are amended for consistency with the amendment to claim 29.

3. Claim 62 is amended to replace "device" and "catheter" with "tissue penetrating structure" and "catheter body," respectively.

4. Claim 68 is amended in a manner similar to claim 29.

5. Claims 69 and 70 are amended for consistency with the amendment to claim 68.

Now, with respect to the matters raised in the present action:

A. Claim 62 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite, for failing to particularly point out and distinctly claim the subject matter of the invention.

It is submitted that in view of the foregoing amendment, claim 62 meets the requirements of 35 U.S.C. § 112, second paragraph.

B. Claims 29, 44, 60, 65-68, 71-75 and 78 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 5,411,535 (Fujii et al.).

The Fujii patent describes a cardiac pacemaker using wireless transmission. The pacemaker includes a main body incorporating a transmitter for emitting modulated pulses in the form of a transmission wave 105. The pacemaker includes at least one pacing electrode secured to the heart, either in the atrium or in the ventricle. Each electrode has a receiver tuned to

receive wave 105, and a demodulating section for converting the incoming wave into voltages applied to a tissue stimulating electrode portion of the electrode. With reference to Figures 9-11, the pacing electrode can be releasably coupled to a catheter used to carry the electrode into the heart. A screw 401 is mounted inside the pacing electrode through a threaded screw portion 413. The screw can be rotated relative to the electrode using a screw handle 405 contained in the catheter, to cause a coiled portion or auger 412 of the screw to penetrate tissue, and thus help secure the pacing electrode.

Claim 29 defines an apparatus including an electrically inactive implant with an element for penetrating cardiac tissue to secure the implant at a designated site in a heart to modify electrical action in the cardiac tissue. The claimed apparatus further includes a delivery device releasably coupled to the implant to allow use of the delivery device to deliver the implant to a designated site in the heart and to allow a withdrawal of the delivery device after securing the implant.

Thus, the apparatus of claim 29 is used to secure an implant that is electrically inactive, yet useful in a variety of biotherapeutic applications. With reference to U.S. Patent No. 5,551,427, to address the types of electrical abnormalities illustrated in Figures 1-3, electrically inactive implants are secured in cardiac tissue at designated sites as illustrated in Figures 19-22. See column 2, lines 28-63 and column 17, lines 7-60 of the specification regarding Figures 1-3 and Figures 19-22, respectively.

In contrast, the Fujii patent neither discusses these types of biotherapeutic applications, nor indicates that its devices might be employed in such applications. Rather, Fujii is focused upon cardiac pacemakers - devices which by their very nature are electrically active.

In connection with this rejection, it is contended in the present action (page 3) that Fujii's element 412 is an electrically inactive device capable of modifying electrical action, that the element "attaches electrode 420 to the heart," and that the device is releasably coupled to catheter 410.

This contention is respectively traversed.

As for the contention that Fujii's element 412 (coiled portion 412) is electrically inactive, the Fujii patent does not explicitly state that coiled portion 412, or screw 401 that includes the coiled portion, is an electrically inactive component. Fujii does not disclose any purpose, such as

the biotherapeutic applications noted above, that would require the screw or its coiled portion to be electrically inactive. The function disclosed for Fujii's screw and its coiled portion; namely, anchoring the electrode to the endocardium by virtue of coiled portion entry into tissue, does not require these components to be electrically inactive. Conversely, the function of Fujii's electrode, i.e. delivering stimulating pulses to the endocardium, clearly requires an electrically active component. An electrically active screw and coiled portion would be consistent with this function.

Further, Fujii discloses that its electrode portion (125 in Figures 2 and 6, 424 in Figures 9 and 10) is used to stimulate the endocardium. See column 6, lines 7-8. Fujii teaches that electrode portion 424 is pressed against the endocardium (column 5, lines 9-11), yet also shows lead lines (Figures 9 and 10) that run from reference character 424 to the proximal portion of electrode 420. This suggests that the electrode portion constitutes virtually the entire body of electrode 420, including the threaded portion of the electrode contiguous with screw portion 413 of screw 401. Fujii also teaches that screw 401 is electrically conductive. See column 5, lines 41-42. This indicates that screw 401 (including coiled portion 412) is electrically active by virtue of its electrical coupling to electrode portion 424.

These disclosures in Fujii refute the contention that coiled portion 412, or more generally screw 401, is electrically inactive.

Should the examiner continue to contend that Fujii discloses an electrically inactive component in the form of coiled portion 412, screw 401, or otherwise, he is respectfully requested to specify where the Fujii specification supports that contention.

Accordingly, it is submitted that the Fujii patent fails to anticipate the apparatus defined in claim 29.

Claims 44 and 60 depend on claim 29, and are allowable for the reasons given in support of claim 29. Claim 44 is patentable, further, for the failure of Fujii to teach or suggest an electrode at the distal end of the delivery device. Regardless of whether catheter 410 or screw handle 405 is proposed as the component equivalent to the claimed delivery device, there is no disclosure of an electrode at the distal end of such component for sensing electrical action in the cardiac tissue.

New claim 79 further defines claim 29 in that the implant further includes a coupling structure adapted to form a releasable coupling of the implant with the delivery device, and that the delivery device is operable through the releasable coupling to cause the element to penetrate cardiac tissue to secure the implant.

None of Fujii's components teaches or suggests the claimed coupling structure. Coiled portion 412 lacks any coupling structure for a releasable coupling to a delivery device. Screw 401 has a rod-shaped portion 414 which fits into an opening 421 of the catheter and has a recess 404b at its proximal end to receive a connecting portion 403a of screw handle 405. The screw/screw handle coupling is for torque transmission. However, this coupling cannot be made until the pacing electrode is delivered to the heart, brought to its intended placement site, and pressed against endocardial tissue. Finally, Fujii's electrode 420 does not teach or suggest the claimed coupling structure, because it is electrically active.

Thus, Fujii teaches different couplings for delivering the electrode and for securing the electrode. The coupling suitable for electrode delivery is inoperable to secure the electrode. The coupling needed for securing the electrode cannot be established until after electrode delivery and placement.

Claim 65 defines a process for locally modifying electrical action in tissue in the region of the heart, including using a delivery device to introduce a biocompatible, electrically inactive implantable device including a tissue penetrating element into the region of the heart and guide the implantable device to a designated site. The tissue penetrating electrode is caused to penetrate tissue to secure the implantable device at the designated site. With the implantable device so secured, the delivery device is decoupled and withdrawn from the designated site.

The devices disclosed in Fujii are incapable of performing the claimed process. There are no equivalents in Fujii to the claimed electrically inactive implantable device. Screw 401, and likewise coiled portion 412, appear to be electrically active, as pointed out above. If Fujii's electrode 420 is likened to the implantable device in claim 65, it likewise fails to satisfy the feature that the implantable device is electrically inactive.

Accordingly, the process defined in claim 65 is patentable over Fujii.

Claims 66 and 67 depend on claim 65, and are allowable along with claim 65.

New claims 80-83 depend on claim 65, and for that reason are allowable. Claims 80-82 are patentable further for the failure of Fujii to teach the claimed subject matter regarding locally modifying electrical action in tissue, and sustained release of a drug or antiarrhythmic agent. Claim 83 is patentable for the reasons given in support of claim 79.

Claim 68 incorporates the features discussed above in connection with claim 29, and accordingly is allowable for the reasons given in support of claim 29. Claim 71 depends on claim 68, and is patentable along with claim 68.

New claims 84-87 depend on claim 68. Claims 84-86 are patentable for the reasons given in support of claims 80-82. Claim 87 is patentable for the reasons given in support of claim 83.

Claim 72 is drawn to an apparatus implantable in tissue at a designated site in the region of the heart. The apparatus includes a biocompatible, electrically inactive implantable device comprising a tissue penetrating element. The implantable device further comprises a coupling structure for releasably coupling the implantable device to a delivery device, to enable use of the delivery device to deliver the implantable device to the region of the heart, to position the implantable device at the designated location, and to cause the penetrating element to penetrate tissue to secure the implantable device at the designated site. The coupling structure further is adapted to allow a disengagement and removal of a delivery device from the implantable device after the implantable device is secured.

Regardless of how the components disclosed in Fujii may be considered to establish a coupling between an "implantable device" and a "delivery device" for purposes of delivery, such coupling clearly fails to enable use of the delivery device to cause the penetrating element to penetrate tissue to secure the implantable device. This failure in the coupling is demonstrated by the need to establish two added couplings before screw 401 can be rotated to cause coiled portion 412 to penetrate tissue. The first added coupling is established by using the catheter to press electrode portion 424 against the endocardium to fix the catheter against rotation. The second added coupling is established by pressing screw handle 405 against connection portion 414 of the screw, while the electrode remains pressed against the endocardium, so that torque can be transferred from screw handle 405 to the screw. See column 5, lines 6-16.

Thus, Fujii's "delivery" coupling cannot be used to secure the electrode, and Fujii's "securing" coupling cannot be used to deliver the electrode.

Further, as explained above in connection with claim 29 and claim 68, the Fujii patent fails to teach an implantable device that is electrically inactive.

Accordingly, the subject matter of claim 72 is patentable over the Fujii patent.

Claims 73-75 and 78 depend upon claim 72 and are allowable with claim 72.

Claims 88-90 depend on claim 72, and further are patentable for the reasons given in support of claims 80-82 and claims 84-86.

New Claim 91 is substantially similar to claim 43 written in independent form. New Claim 93 is substantially similar to claim 59 written in independent form. It is submitted that these claims are allowable, as are their respective dependent claims 92 and 94.

To summarize, it is submitted that claims 27-94 incorporate subject matter patentable over the prior art of record, and define that subject matter with the clarity and precision required by 35 U.S.C. § 112, second paragraph. An early and favorable action allowing claims 29, 43-46, 58-60, 62, and 65-78 and new claims 79-94, along with presently allowed claims 27-28, 30-42, 47-57, 61, and 63-64, is respectfully requested.

Respectfully submitted,

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Dated: January 3, 2005

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